

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Glen Jorgensen et al.  
Serial No: To be assigned  
Filed: Herewith  
For: FLUID MANAGEMENT SYSTEMS

COMMISSIONER OF PATENTS  
WASHINGTON, D.C. 20231

Sir:

**PRELIMINARY AMENDMENT**

Please amend the specification and claims as follows. The incorporated/added text and claims below are taken verbatim from related U.S. Application Serial No. 09/082,341 (attorney docket no. Z0090/7016) which was incorporated by reference in its entirety in the parent to this continuation application and filed simultaneously therewith on May 20, 1998 (copy attached hereto).

**IN THE SPECIFICATION:**

On page 1, line 8, after the word "application" insert -- is a continuation of co-pending parent U.S. Application Serial No. 09/082,201 filed May 20, 1998 entitled Fluid Management Systems and --

On page 1, line 8, after the word "of", delete "pending"

On page 1, line 11, after "((" insert -- U.S. Application Serial No. 09/081,733, filed May 20, 1998, --

On page 1, line 12, after "((" insert -- U.S. Application Serial No. 09/082,200, filed May 20, 1998, now abandoned, --

On page 1, line 13, after "((" insert -- U.S. Application Serial No. 09/082,086, filed May 20, 1998, --

On page 1, line 14, after "((" insert -- U.S. Application Serial No. 09/082,341, filed May 20, 1998, now abandoned, --

On page 3, between lines 11 and 12, insert the following:

09/082,341 - 10/08/98

The present invention is a method or an apparatus for interactively processing biological cells maintained in a sterile environment. Furthermore, the invention provides superior means for enzymatically converting red blood cells of groups A, B, or AB to group O. The described cell processing apparatus and method also provide superior means for processing other blood cells such as white blood cells, stem cells, platelets or plasma for transfusion or transplantation. The invention may also be used for separating culture fluid from micro-organisms in the production of biopharmaceuticals. In each case, the cell processing method or apparatus can adjust the processing algorithm based on the type of the processed cells or the cell amount. Furthermore, the cell processing method or apparatus assure uniform and reproducible processing conditions for the processed cells regardless of the processed cell amount.

In one aspect, an apparatus for interactively processing biological cells maintained in a sterile environment includes a supply module, a cell module, a processing module, a set of conduits, a plurality of valves, a plurality of sensors and a control module. The supply module is constructed and arranged to provide selected amounts of process chemicals. The cell module includes a cell sensor for measuring an amount of the biological cells supplied for processing to the processing module. The processing module is constructed and arranged to process said biological cells. The conduits connect the supply module, the cell module and the processing module in a sterile manner and the valves control the transfer of the biological cells and the process chemicals between the modules. The sensors are constructed and arranged to detect the transfer of the biological cells and the process chemicals. The control module is operatively connected to the valves, the sensors and the processing module. The control module also receives data from the cell sensor and controls the transfer and the processing of the biological cells based on the cell sensor data, wherein the modules are constructed and arranged to prevent unwanted contamination of the cells.

This aspect may include one or several of the following features:

The cell sensor includes a weight sensor constructed and arranged to weigh the supplied amount of the biological cells. The cell sensor includes a volume sensor constructed and arranged to measure volume of the supplied amount of biological cells.

The control module is further arranged to calculate amounts of the process chemicals based on the cell sensor data. The control module is further arranged to select an algorithm for processing of the cells based on the cell sensor data.

The supply module includes several containers constructed and arranged to hold the process chemicals, wherein at least some of them are in a liquid state. The process chemicals include an enzyme solution. The process chemicals include a saline solution.

The processing module includes a processing vessel constructed and arranged to vary its volume relative to a volume of the process chemicals and the cells transferred to the vessel for processing. The processing module may include a centrifuge. The centrifuge is constructed and arranged to vary its volume by receiving a filling fluid arranged to occupy a selected volume. The filling fluid may be an expressor fluid designed to selectively express the process chemicals or the cells during centrifugation. The processing module is constructed to agitate, heat, cool or mix the processing chemicals and the cells.

The sensors include an optical sensor, a pressure sensor, a mass flow meter, a weight sensor, a temperature sensor, a sensor, a volume sensor, a density sensor, a viscosity sensor or an electrical resistance sensor.

The interactive system may further include a pump constructed and arranged to advance the material from the supply module to the processing module inside the conduits.

The supply module may further include at least one supply sensor constructed and arranged to measure the amount of at least one of the process chemicals transferred to the processing module. The supply sensor includes a mass sensor, a mass flow meter, a volume sensor or a density sensor.

Another aspect is a method of controlling operation of a cell processing system comprising a control module, a processing module connected in a sterile manner by a set of conduits to a cell module and to a supply module that provides selected process chemicals, and several sensors providing process data to the control module. The method includes providing in the cell module biological cells; measuring an amount of the cells supplied to the processing module for processing; providing in the supply module process chemicals according to a processing algorithm; dispensing from the supply module the process chemicals to the processing module based on the measured amount of the cells; processing the cells in the processing module; and storing the processed cell while preventing unwanted contamination of the cells during the dispensing and the processing.

This method may include the following features: The dispensing from the supply module includes calculating amounts of the process chemicals based on the measured amount of the

10. The interactive system of claim 9 wherein said cell sensor includes a weight sensor constructed and arranged to weigh said supplied amount of said biological cells.
11. The interactive system of claim 9 wherein said cell sensor includes a volume sensor constructed and arranged to measure volume of said supplied amount of said biological cells.
12. The interactive system of claim 9 wherein said control module is further arranged to calculate amounts of said process chemicals based on said cell sensor data.
13. The interactive system of claim 9 wherein said control module is further arranged to select an algorithm for said processing based on said cell sensor data.
14. The interactive system of claim 9 wherein said supply module includes several containers constructed and arranged to hold said process chemicals at least some of them being in a liquid state.
15. The interactive system of claim 9 wherein said process chemicals include an enzyme solution.
16. The interactive system of claim 9 wherein said process chemicals include a saline solution.
17. The interactive system of claim 9 wherein said processing module includes a processing vessel constructed and arranged to vary its volume relative to a volume of said process chemicals and said cells transferred to said vessel for processing.
18. The interactive system of claim 9 wherein said processing module includes a centrifuge.
19. The interactive system of claim 18 wherein said centrifuge is constructed and arranged to vary its volume by receiving a filling fluid arranged to occupy a selected volume.
20. The interactive system of claim 19 wherein said filling fluid is an expressor fluid designed to selectively express said process chemicals or said cells during centrifugation.
21. The interactive system of claim 9 wherein said processing module is constructed to agitate, heat, cool or mix said processing chemicals and said cells.
22. The interactive system of claim 9 wherein said sensors include an optical sensor.
23. The interactive system of claim 9 wherein said sensors include a pressure sensor.
24. The interactive system of claim 9 wherein said sensors include a mass flow meter.
25. The interactive system of claim 9 wherein said sensors include a temperature sensor.

26. The interactive system of claim 26 wherein said temperature sensor includes a IR sensor constructed and arranged to measure a temperature of said cells and said process chemicals inside said processing module.

27. The interactive system of claim 9 further including a pump constructed and arranged to advance said material from said supply module to said processing module in said conduits.

28. The interactive system of claim 9 wherein said supply module further includes at least one supply sensor constructed and arranged to measure the amount of at least one of said process chemicals transferred to said processing module.

29. The interactive system of claim 28 wherein said supply sensor includes a mass sensor.

30. A method of controlling operation of a cell processing system comprising a control module, a processing module connected in a sterile manner by a set of conduits to a cell module and to a supply module that provides selected process chemicals, and several sensors providing process data to said control module, said method including

providing in said cell module biological cells;  
measuring an amount of said cells supplied to said processing module for processing;  
providing in said supply module process chemicals according to a processing algorithm;  
dispensing from said supply module said process chemicals to said processing module based on said measured amount of said cells;  
processing said cells in said processing module; and  
storing said processed cell, whereby preventing unwanted contamination of said cells during said dispensing and said processing.

31. The method of claims 30 wherein said dispensing from said supply module includes calculating amounts of said process chemicals based on said measured amount of said cells.

32. The method of claims 30 wherein said measured amount of said cells supplied for processing is less than the amount of said biological cells provided in said cell module.

33. A method of processing biological cells in a sterile environment comprising:  
providing biological cells;  
measuring an amount of said cells supplied for processing;  
providing process chemicals according to a processing algorithm;

dispensing said process chemicals based on said measured amount of said cells;  
processing said cells; and  
storing said processed cell, whereby preventing unwanted contamination of said cells  
during said dispensing and said processing.

34. The method of claims 33 further comprising selecting said processing algorithm  
based on said provided cells.

Respectfully submitted,

By: 

M. Lawrence Oliverio, Reg. No. 30,915

Wolf, Greenfield & Sacks, P.C.

600 Atlantic Avenue

Boston, MA 02210

(617) 720-3500

Docket No.: Z0090/7027

Date: December 1, 2000

xnddx